Utah Department of Health

CLINICAL LABORATORY BULLETIN May 2007

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING:

Adam Isabella	Molecular Biology
Alex James	Molecular Biology

NOTEWORTHY

✓ **Reduce Send-Out Test Errors:** One facility was surprised by the results of an internal audit on error rates for tests sent to reference labs. One premise was there would be fewer order errors if they used specific test order codes rather than a "miscellaneous" code. The facility and CAP's resource committee analyzed the Q-Probe study "Send-Out Test Order Accuracy" and found just the opposite. The error rate was 5.6% when a specific test code was used and 3.9% when the miscellaneous code accompanied the request.

How can you minimize these errors?
Adequately train test referral personnel.
Improve communications between test referral personnel and laboratory technical staff.
Communicate with the ordering clinician.
Order esoteric tests electronically from the reference lab's list that includes the order code and information on testing indications / limitations.
Order tests with a miscellaneous test code that provides space for a free text description.

✓ **Misdiagnosis with urine pregnancy (hCG) tests:** Case studies presented in the May, 2007 issue of Lab Medicine point to a diagnostic problem with urine hCG tests. Two women were ultimately diagnosed with descending colon cancer and cervical cancer respectively. The remarkable finding was a positive hCG test for both women. Standard protocol requires ruling out pregnancy for any woman (in the correct age group) presenting with vaginal bleeding or lower abdominal pain. The false positive results were due to cross-reacting hCG fragments in the urine of both patients. When a hCG result does not fit the clinical picture, a confirmatory quantitative serum test is necessary.

✓ **Serum creatinine measurements:** An article in the Arch Pathol Lab Med 2005; 129: 297-304 by Dr. Greg Miller (Virginia Commonwealth University) points out a need to standardize creatinine testing. CAP sent a special specimen to 5,624 labs (representing 50 different instrument/method combinations) to evaluate results harmonization. The mean result used to judge accuracy was obtained by higher-order isotope dilution mass spectrometry.

CONTENTS

The author concluded 60% of the 50 peer groups had significant test bias. The variability was related directly to test manufacturer rather than method type. Without manufacturer standardization, estimated glomerular filtration rates calculated from serum creatinine test results will continue to be inaccurate.

✓ **Urine cultures contaminated?:** Are too many urines in your facility reported >100,000 cfu/mL – probable contaminants? Up to 40% as in some clinical settings? Nothing can be done? Not so! Consider the results of one multi-site study:

Oral instructions decreased male patient contamination rates, but not female rates.

Written instructions lowered the rate for both male and female patients.

Centralized processing areas decreased male patient contamination rates.

Refrigerating samples that may take longer than 30 minutes from collection to plating made the biggest contamination rate reduction.

Pre-screening urines to determine which ones need cultures **increased** the contamination rate. So a facility that employs pre-screening can do the visual cloudy/clear test and decrease the contamination rate. Just don't do what one lab did – pour urine from the container onto a urinalysis dipstick to prevent contaminating the sample. While the sample was protected, the urinalysis results were inaccurate.

✓ **Platelet gels help healing process:** An article in the January, 2007 Lab Medicine relates the preparation, benefits and uses for autologous platelet gels. A platelet gel may be prepared from the patient's blood just before surgery. Applied to wounds it acts like a bandage – only better since a patient is seldom allergic to their own blood. Uses cited include: adding gel to bone graft material to make it more bioactive; preventing CSF leakage following neurosurgery; aiding skin graft procedures, packing material for paranasal sinus surgery; orthopedic surgery; chronic wounds (i.e. diabetic ulcers); burns; snake and spider bites; vascular access grafts, aortic aneurysms, bypass graft surgeries; macular hole surgeries; retroperitoneal lymph node dissections; and heel injections to treat plantar faciitis. WOW!

✓ **ESR at home:** The winner of the 2004 ASCLS Student Research Paper Award (Sarah E. Douglas) developed a micro-erythrocyte sedimentation rate (ESR) system with potential for patient home care use. The report was published in the Winter 2007 issue of Clinical Lab Science. Copies of the entire paper are available from Tim R. Randolph, MS CLS(NCA). Phone 314.977.8688 or email randoltr@slu.edu.

New homes should come equipped with a special "clean" room to be used for laboratory self-testing!

✓ **Vaccine storage and handling:** For you laboratory professions whose multi-tasking duties include vaccinating patients, check out the article in the February 12, 2007 issue of Advance (www.advanceweb.com/MLP). The article by Donna L. Weaver, MN, RN recommends following the vaccine manufacturer's instructions from the package insert as well as the ACIP recommendations found at www.cdc.gov/nip/publications/acip-list.htm. Ms. Weaver states some vaccines require storage at refrigerator temperatures while others must be kept frozen (LAIV & MMRV). Some vaccines can be pre-filled in the syringe, others must be drawn up just before administration. Never put more than one vaccine into one syringe unless the manufacturer specifically recommends it. Make sure you have the right needle length for the recommended injection route. If two or more vaccines must be given in the same limb, be certain there is a least one inch between injection sites. Training materials are available from the Immunization Action Coalition at www.immunize.org. They include a video, posters and other related resources.

✓ **Monitor the effectiveness of your BSC UV lamp with bacteria:** Brian J. Harrington, PhD and Michael Valigosky, MS wrote an article in the March 2007 issue of Lab Medicine on an inexpensive way to monitor your UV lamp output. CDC recommends an ultraviolet (UV) radiation intensity of $40\mu W/cm^2$ in the middle of the work area to ensure proper decontamination in a biological safety cabinet (BSC). The authors used *E. coli* and *Staph aureus* (UV kill dose = 6,600); *E fecalis* (UV kill dose = 10,00) and *P. aeruginosa* (UV kill dose = 3,900) to estimate lamp output. They conclude this method can "closely estimate the UV lamp output".

✓ **Preparing bone or biomaterial implant tissues for histological examination?:** Deidre Hart and Nancy Troiano, MS give tips on sectioning these difficult samples in the April 23, 2007 issue of Advance. Any tissue that must be embedded in plastic (such as MMA [methylmethacrylate]) requires special sectioning blades and technique. The authors recommend tungsten carbide blades (second only to diamond blades for strength), correct cutting speed and adjusted clearance angle to yield the best sectioning results and to increase the cutting edge life. See the entire article at www.advanceweb.com/MLP.

✓ **Anticoagulation therapy – old tests new drugs:** An article in the Archives of Pathology Laboratory Medicine (2004:128:1142-1145) discusses the effects of direct thrombin inhibitors on coagulation testing. The authors conclude clinicians must use caution in interpreting coagulation test results for patients receiving newer anticoagulants such as argatroban, bivalirudin and lepirudin. Normal ranges for INR were determined by clinical outcome on patients receiving thrombin inhibitors. Newer drugs prevent coagulation in a different manner. Studies are few and on small numbers of patients using these drugs and tested with current, standard coagulation methods.

FROM THE PATIENT'S CHART

"Patient has two teenage children, but no other abnormalities."

☆ Feature ☆

Clinical Laboratory Improvement Amendments (CLIA)

Calibration and Calibration Verification Brochure #3

What is calibration, and how do I do it?

What is the difference between calibration and calibration verification?

Calibration is the process of testing and adjusting the instrument or test system readout to establish a correlation between the instrument's measurement of the substance being tested and the actual concentration of the substance.

Calibration verification means testing materials of known concentration in the same manner as patient specimens to assure the test system is accurately measuring samples throughout the reportable range.

Calibration

Is there a new requirement for calibration?
No, the CLIA requirements for calibration have not changed. The laboratory is responsible for performing calibration as directed by the manufacturer's test system instructions, and when calibration verification of the test system

(see below) does not produce acceptable results.

Reminder: Be sure to document in the laboratory's records **each** time you perform calibration.

Is calibration required for every procedure my laboratory performs?

No, calibration is not required for the following:

- Manual procedures—such as microbiology cultures and tilt-tube prothrombin time test systems.
- Microscopic procedures—such as KOH preparations, pinworm preparations, urine sediment analysis, all manual cell differential procedures, and manual cytology screening procedures.
- Procedures involving an instrument in which calibration is not practical—such as prothrombin procedures.

How do I perform calibration?

The test system's instructions should describe the process for performing calibration, as well as when and how often it is to be performed.

What materials should I use to perform calibration?

The test system's instructions should specify the number, type and concentration of the calibration material to use.

Calibration material is a solution that contains a known amount of analyte. In the past, the term "standard" was generally used to mean calibration material.

Calibration Verification

Is there a new requirement for calibration verification?

No, the laboratory has always been responsible for calibration verification or "checking" calibration. However, the process for checking a moderate complexity test system's calibration was not defined. The regulations now describe how and when calibration verification is to be performed for nonwaived (moderate and high complexity) tests.

Reminder: Be sure to document in the laboratory's records **each** time you perform calibration verification.

When must I check a test system's calibration (perform calibration verification)?

Once every 6 months (or more frequently if specified in the test system's instructions) and whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers, **unless** the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
- There is major preventive maintenance or replacement of critical parts that may influence the test's performance. This includes when the laboratory sends a test system to the manufacturer for repairs. The laboratory must check the calibration of a repaired test system before resuming patient testing and reporting results.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
- The laboratory has determined that the test system's reportable range for patient test results should be checked more frequently.

Reminder: The laboratory is responsible for verifying calibration on factory-calibrated test systems that cannot be calibrated by the user.

What materials should I use to perform calibration verification?

A variety of materials with known concentration may be used to verify calibration, for example, commercially available standards

or calibration materials, proficiency testing samples with known results, control materials with known values, or patient specimens with known values.

Since the purpose of calibration verification is to check whether the test system is providing accurate results throughout the reportable range, three levels should be tested—one at the high end of the reportable range, one at the low end of the reportable range, and one near the midpoint of the reportable range.

Are there exceptions to calibration verification requirements?
Yes, there are exceptions:

- Control activities routinely used to satisfy the CLIA requirements at §493.1256 do not satisfy the calibration verification requirements. However, there is an exception for automated call counters. For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operations, and tests two levels of control materials each day of testing. Provided the control results meet the laboratory's criteria for acceptability.

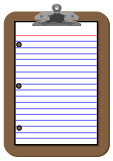
- If the test system's calibration procedure includes three or more levels of calibration material, **and** includes a low, mid, and high value, **and** is performed at least once every six months, then the requirement of for calibration verification is also met.

What should I do if calibration verification fails?
If calibration verification results are unacceptable, you must repeat the test system's calibration procedure. After repeating the calibration procedure, it is good laboratory practice to run controls before resuming patient testing.

If the test system is factory-calibrated, consult with the manufacturer of the test system.

Is there a difference in the requirements for calibration and calibration verification based on the complexity of the test system?
No. The CLIA calibration and calibration verification requirements are the same for all nonwaived test systems.

Where can I find additional information about the CLIA requirements pertaining to calibration and calibration verification?
Refer to "The State Operations Manual," Appendix C-Interpretive Guidelines, Calibration and Calibration Verification Procedures (§493.1255) available on the CMS web site at: www.cms.hhs.gov/clia



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Medi-Lab Performance Strep A Twist Rapid Test & Dipstick

°Jant Pharmacal Corporation Accutest TSH (whole blood)

°Redwood Toxicology Laboratory Reditest Home Drug Test & 6 cassette substance abuse screening device

°Abaxis Piccolo Blood Chemistry Analyzer and xpress (general chemistry 6 & 13 panels)

°Immuno Detector BioSign Mono WB

Equals

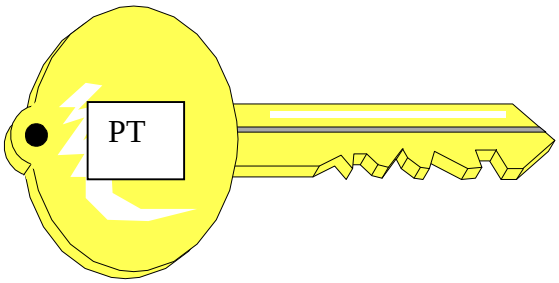
"1millionth of a fish: 1 microfiche"

Quality Assessment Spotlight

As a new feature, we will present an outstanding example from one of your laboratories on a quality assessment success that improves patient test outcome. Please submit your examples to Rebecca by fax (801. 584.8501) or email rchristiansen@utah.gov.

In response to a CLIA survey deficiency to alter the expiration date for CBC reagents once they are opened, the technical consultant (TC) went a step further. She noted the manufacturer stated the reagents, stored at room temperature (59 - 77° F), outdated 60 days after opening. As the staff recorded daily room temperatures, the TC found the room temperature was 76° F three consecutive days and the full heat of summer hasn't come yet. The facility is now switching out the reagent after 30 days so test results are not compromised by substandard reagents.

Kudos Donelle Baxter, TC, Hurricane Health Center

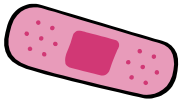


The American Proficiency Institute (API) reported their evaluation of the long-term impact of proficiency testing (PT) on laboratory performance in the April 2007 issue of Lab Medicine. Their ten-year review revealed some interesting findings.

API serves mostly smaller facilities – more than 13,000 physician's offices, clinics and hospitals with fewer than 100 beds. The article concludes: "Failure rates for chemistry and hematology analytes declined significantly during the 10-year period. Failure rates for microbiology analytes also declined but remained above 5% in 2004 for positive genital/GC cultures, positive urine cultures, and Gram stains."

Conclusion: "The data indicates that statistics for unsatisfactory laboratory performance may fail to detect significant problems."

Read the article at www.labmedicine.com.



SAFETY

FDA Recalls – Troponin Assays

March 8, 2007 FDA initiated a recall for Abbott ARCHITEST(r) STAT Troponin-I April 27, 2007. The assay may give falsely elevated or lowered patient results at or near the lower reportable range (<0.1 ng/mL).

April 27, 2007 FDA initiated a recall for Ortho-Clinical Diagnostics, Inc VITROS Immunodiagnostic Products Troponin I Reagent Packs - lots 3151 and 3170. These lot numbers were manufactured between January 5 and February 1, 2007. These reagent packs were noted to cause false negative test results at low levels (no numbers given).

FDA recalls are posted on their website at www.fda.gov/cdrh/recalls.

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Summer time brings outdoor fun and indoor houseflies. The Maryland Department of Health & Mental Hygiene's newsletter – Critical Link – from October 2006 warns about houseflies transmitting enterococci to food. The newsletter cited a Kansas study that identified enterococci in 97% of houseflies collected in fast food restaurants. They found 88.2% were *Enterococcus faecalis* and *facium*. These organisms are the most common cause of enterococcal infections in humans. Watch out for foodborne illness from common bacteria.

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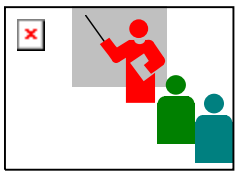
Todd Smith, Associate Editor for Advance reported on a personal experience with the current "hot topic" – patient safety. He was hospitalized and had a peripherally inserted central catheter (PICC) line in one arm. When it became infected, the physician had a sign put up to prevent blood draws from the affected arm. A phlebotomist disregarded the "upper arm" restriction notice and was going to draw from the wrist vein. Todd asked her to check with his nurse. She came back, said the nurse approved, and proceeded with the draw. The nurse had not been contacted and was upset as she feared an emboli could dislodge and potentially kill him. Fortunately, it didn't as Todd is alive to tell the story. His conclusion – "Some facilities would not categorize my situation as a medical error, as many use outcome-dependent definitions as opposed to a process-dependent approach. Therefore, it is not likely that corrective strategies would be implemented if there is not adverse patient effect."

Ponderables:

Why do you have to "put your two cents in" . . . but it's only a "penny for your thoughts"? Where's that extra penny?

CONTINUING EDUCATION



CLSI Leadership Conference Web Casts

Facing the Challenge: Practical Approaches to Evaluate Analytical Performance

I	June 12, 2007
II	June 26, 2007
III	July 10, 2007

For registration information contact the NLTN at 800.536.6586.

Understanding Our Universe

"There is a theory which states that if ever anybody discovers exactly what the Universe is for and why it is here, it will instantly disappear and be replaced by something even more bizarre and inexplicable.

There is another theory which states that this has already happened."

Douglas Adams